

**REMARKS**

Reconsideration of this patent application in view of the present amendment and these remarks is respectfully requested.

**I. Claims**

Claims 1-33 and 35-40 are currently pending. Claim 34 is cancelled.

Claims 1-2, 5-16, 19-23 and 25-33 stand rejected. Claims 3, 4, 17, 18 and 24 have been objected to. Claim 1 is now amended. Claims 35-40 have been added.

Reconsideration of the above-identified application in view of the amendments to claim 1 and the following remarks is respectfully requested.

**1. Rejection of Claims 1-2, 5-12, 15-16, 19-22 and 25-27 Under 35 U.S.C. §103(a)**

Claims 1-2, 5-12, 15-16, 19-22 and 25-27 have been rejected as unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,156,067 to Bryan et al. (hereinafter, "Bryan"). It is respectfully submitted that claim 1, as amended, and claims 2, 5-12, 15-16, 19-22 and 25-27 define over Bryan.

Claim 1, as amended, recites a method for replacing a damaged spinal disc between first and second vertebrae of a spinal column. The method comprises connecting a first mounting member with the first vertebra of the spinal column. The method also comprises moving an artificial disc between the first and second vertebrae and into engagement with the first mounting member to guide the artificial disc into position between the first and second vertebrae. The artificial disc includes a resilient core having a first surface and a second surface. The artificial disc also includes a first retaining member fixedly connected to the first surface of the resilient

core, and a second retaining member fixedly connected to the second surface of the resilient core. The first retaining member has an outer surface engageable with the first vertebra of the spinal column and an inner surface facing the first surface of the resilient core. The second retaining member has an outer surface engageable with the second vertebra of the spinal column and an inner surface facing the second surface of the resilient core.

The Office Action states that Bryan discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Bryan comprises an artificial disc that includes (a) a resilient core (central portion 24 of body 20 of Bryan) having a first surface and a second surface, (b) a first retaining member (support 32 of Bryan) connected to the first surface of the resilient core, and (c) a second retaining member (support 34 of Bryan) connected to the second surface of the resilient core. The Office Action also states that the first retaining member of Bryan has an outer surface (surface 52 of Bryan) engageable with a first vertebra of the spinal column and an inner surface (surface 62 of Bryan) facing the first surface of the resilient core. The Office Action further states that the second retaining member of Bryan has an outer surface (surface 54 of Bryan) engageable with the second vertebra of the spinal column and an inner surface (surface 64 of Bryan) facing the second surface of the resilient core. Lastly, according to the Office Action, the apparatus of Bryan comprises a first mounting member (cannulated screw device 82 of Bryan, which comprises screw 92 and screw anchor 102).

The Office Action asserts that Bryan discloses connecting a first mounting member (screw anchor 102 of Bryan) with a first vertebra of a spinal column and moving an artificial disc into position between first and second vertebrae. The Office Action notes that Bryan does not explicitly disclose moving the artificial disc into engagement with the first and second mounting members to guide the artificial disc into position between the first and second vertebrae. Nonetheless, the Office Action asserts that the opening in the artificial disc of Bryan must be lined up with the opening in the anchor of Bryan for the entire device to be properly implanted. As such, according to the Office Action, the opening in the anchor acts as a guide, visual or otherwise, when the artificial disc of Bryan is inserted and comes into contact with the anchor.

It is respectfully submitted that Bryan does not disclose the method of claim 1, as amended, nor does it render the method of claim 1 obvious to one of ordinary skill in the art as required by 35 U.S.C. §103(a).

First, the supports 32 and 34 of Bryan are not fixedly connected to the adjacent surfaces of the nuclear central portion 24 of body 20, as recited in amended claim 1. This lack of connection is pointed out at column 8, lines 3-5 and column 7, lines 10-15 of Bryan. The supports 32 and 34 of Bryan merely contact the adjacent surfaces of the nuclear central portion 24 so that relative sliding motion between the supports and the core is possible.

Second, as stated at column 7, lines 2-9 of Bryan, the concaval-convex elements of Bryan (which, as described at column 4, lines 10-19, are the supports 32 and 34) are inserted between two milled vertebrae 12 and 14. The elements 32 and

34 are then attached by anchors 102 and 104 to the bone. As shown in Fig. 3 of Bryan and described at column 4, lines 25-34 of Bryan, the anchors 102 and 104 receive screws 92 and 94 that extend through openings in the elements 32 and 34. Thus, the endoprosthesis 18 of Bryan is fully inserted between the two vertebrae before the support 32 contacts the screw anchor 102, which the Office Action asserts is part of the first mounting member of Bryan. Because the endoprosthesis 18 of Bryan is fully inserted before contacting the screw anchor 102, the endoprosthesis is not moved into engagement with the first mounting member to guide the endoprosthesis into position between the first and second vertebrae, as required by claim 1.

The Office Action argues that because the screw anchor 102 of Bryan is implanted first and because the opening in the screw anchor and the slot in the leg 72 of support 32 of Bryan must be lined up, the opening in screw anchor 102 acts as a guide when the endoprosthesis 18 of Bryan is inserted and comes into contact with the anchor 102. Claim 1, however, recites "moving an artificial disc ... into engagement with the first mounting member to guide the artificial disc into position between the first and second vertebrae." It is thus the engagement between the artificial disc and the first mounting member that guides the artificial disc into position. The visual alignment process to which the Office Action refers neither requires nor suggests moving an artificial disc into engagement with a first mounting member to guide the disc into position between the first and second vertebrae, as required by claim 1. The Office Action asserts that "the opening in the anchor ... acts as a guide, visual or otherwise, when the artificial disc is inserted" [emphasis

added], but the Office Action fails to articulate what *other* guidance is being provided. It is respectfully submitted that the Office Action is hypothesizing or speculating that alignment between the opening in the screw anchor and the slot in the leg 72 of support 32 of Bryan somehow occurs as the result of engagement between the screw anchor and the endoprosthesis of Bryan without any reasonable basis for such speculation.

Since Bryan neither discloses nor suggests the foregoing elements of amended claim 1, claim 1 is neither suggested nor taught by the proposed combination of references and is allowable over the cited art. Claims 2, 5-12, 15-16, 19-22 and 25-27 depend, directly or indirectly, from amended claim 1 and are allowable for at least the reasons given in the foregoing discussion of claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 2, 5-12, 15-16, 19-22 and 25-27 define over the cited prior art. Withdrawal of this rejection of claims 1-2, 5-12, 15-16, 19-22 and 25-27 is respectfully requested.

**2. Rejection of Claims 13-14 and 28-33 Under 35 U.S.C. §103(a)**

Claims 13-14 and 28-33 have been rejected as unpatentable under 35 U.S.C. §103(a) over Bryan in view of U.S. Patent Application Publication 2002/0183757 to Michelson (hereinafter, "Michelson"). It is respectfully submitted that claims 13-14 and 28-33 define over the cited art.

As to claims 14 and 29, the Office Action states that Bryan discloses engaging a frustoconical surface on an artificial disc with a frustoconical surface on screws of the first and second mounting members of Bryan. Regarding claims 13 and 28, the

Office Action notes that Bryan fails to disclose connecting an artificial disc to first and second mounting members with an interference fit. According to the Office Action, Michelson discloses a method of spinal stabilization in which a resilient stabilization device is connected to at least a first mounting member (a bone screw) with an interference fit (paragraphs 0078 and 0091 of Michelson).

As to claims 30-33, the Office Action notes that Bryan fails to disclose connecting a surgical tool to a first portion a first retaining member and a first portion of a second retaining member by extending a first portion of a surgical tool into a first opening in the first portion of the first retaining member and a second portion of the surgical tool into a first opening in the first portion of the second retaining member. Nonetheless, according to the Office Action, Michelson teaches a method of spinal stabilization in which a resilient stabilization device is positioned by a surgical tool connected to the device by a first portion of the tool extending into a first opening in a first portion of a first retaining member (plate of Michelson) and a second portion of the tool extending into a first opening in a first portion of a second retaining member (plate of Michelson), as disclosed in paragraphs 0079, 0082 and 0091 of Michelson.

Therefore, the Office Action asserts, it would have been obvious to one of ordinary skill in the art to connect the artificial disc of Bryan to the mounting members (screws) of Bryan with an interference fit, as suggested by Michelson, as doing so would reduce the likelihood of screw backout. The Office Action also asserts that it would have been obvious to one of ordinary skill in the art to connect a surgical tool to a first portion of a first retaining member of Bryan and a first portion of

a second retaining member of Bryan, as suggested by Michelson, as doing so would facilitate insertion of the retaining members.

Claims 13-14 and 28-33 depend, directly or indirectly, from amended claim 1. Michelson does not address the deficiencies in Bryan discussed previously with respect to the rejection of claim 1 as being unpatentable under 35 U.S.C. §103(a) over Bryan. Claims 13-14 and 28-33 thus are allowable for at least the reasons given in the preceding discussion of claim 1 and further for the recitations contained in those claims. It is therefore respectfully submitted that claims 13-14 and 28-33 define over the cited art, and withdrawal of this rejection of claim 13-14 and 28-33 is respectfully requested.

**3. Rejection of Claim 23 Under 35 U.S.C. §103(a)**

Claim 23 has been rejected as unpatentable under 35 U.S.C. §103(a) over Bryan in view of U.S. Patent No. 5,584,887 to Kambin (hereinafter, "Kambin"). It is respectfully submitted that claim 23 defines over the cited art.

The Office Action notes that Bryan fails to disclose moving first and second mounting members away from each other to connect the mounting members to first and second vertebrae. According to the Office Action, Kambin discloses a surgical kit containing an implant comprising numerous mounting members, which are grouped together in the kit. Kambin also shows, according to the Office Action, that the mounting members are connected to first and second vertebrae. Therefore, the Office Action asserts, it would have been obvious to one of ordinary skill in the art to provide the artificial disc of Bryan, including mounting members, in a kit with like pieces grouped together such that the surgeon would move the first and second

mounting members away from each other to connect the mounting members to the first and second vertebrae, as suggested by Kambin, as doing so would enhance efficiency during a surgical procedure.

Claim 23 depends indirectly from amended claim 1. Kambin does not address the deficiencies in Bryan discussed previously with respect to the rejection of claim 1 as being unpatentable under 35 U.S.C. §103(a) over Bryan. Claim 23 thus is allowable for at least the reasons given in the preceding discussion of claim 1 and further for the recitations contained in claim 23. It is therefore respectfully submitted that claim 23 defines over the cited art, and withdrawal of this rejection of claim 23 is respectfully requested.

**4. Allowable Subject Matter**

The Office Action indicates that claim 24 was objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. In view of the foregoing remarks concerning the patentability of amended claim 1 from which claim 24 indirectly depends, claim 24 is considered to be in condition for allowance in its present dependent form, and allowance of dependent claim 24 is respectfully requested.

**5. Newly Presented Claims 35-40**

The Office Action indicates that claims 3, 4, 17 and 18 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Claim 35 presents the subject matter of claim 3 in independent



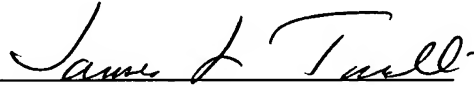
form, together with the subject matter of claims 1 and 2 from which claim 3 depended. Claims 36-40 present the subject matter of claims 4, 15, 16, 17 and 18, respectively, in a form that depends, directly or indirectly, from newly presented claim 35. Consequently, claims 35-40 are considered to be in condition for allowance, and allowance of those claims is respectfully requested.

**II. Conclusion**

In view of the foregoing amendment and remarks, it is respectfully submitted that claims 1-33 and 35-40 define over the cited art. Withdrawal of the rejections of the claims and the passage of the application to issue is therefore requested.

Please charge any deficiency or credit any overpayment in the fees for this matter to our Deposit Account No. 20-0090.

Respectfully submitted,

  
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